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7. 510(k) summary

510(k) Summary

Smartech Co., LTD.

HOLI I scooter

Sponsor's information:

Cycling and Health Tech Industry R&D Center
No. 17, 37th Rd., Taichung Industry Park, Taichung, Taiwan
Contact person: **Dr. Chang Wan-Lan, Director of Testing Department**
Phone: **+886-4-23501100**
Facsimile: **+886-4-23504590**
e-mail: **cwl@tbnet.org.tw**
Date prepared: **February 25, 2005**

Proprietary and Manufacturer information:

Smartech Co., LTD.
No. 3, Kung 10th Rd., Tachia Town, Taichung Hsien, Taiwan
Contact person: **Irene Kuo, President**
Phone: **+886-4-26814881**
Facsimile: **+886-4-26815211**
e-mail: **lungi001@ms5.hinet.net**

Device

Trade name: **HOLI I scooter**
Common name: **Electrical scooter**
Classification name: **Motorized three-wheeled vehicle**
Medical specialty (Panel): **Physical Medicine Device**
Regulation number: **890.3800**
Product Code: **89INI**
Classification: **Class II**

Predicate devices

Manufacture name: **TUNG DENG ENTERPRISE CO., LTD.**
Name: **Be-Mobile 4-Wheeled Electric Scooter, DK S500**

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k number: **K033239**

Date cleared: **12/18/2003**

Intend use of device

HOLI I scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **HOLI I** scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

The **HOLI I** scooter is with a **130 kg (286 lbs)** weight capacity.

The scooter is basic conventional rear wheel drive, rigid frame vehicle that are battery powered. It consists primarily of a welded steel frame, lighting system, a sealed transaxle motor drive system, electromagnetic braking system, electric motor controller, two batteries with an **off-board** charger and an adjustable seat.

It also includes a tiller handle for steering and a **thumb operated potentiometer throttle control lever** to engage and disengage the scooter motion in both the forward and reverse directions.

The scooter is powered by **two 12 volt lead-acid** DC batteries with **27 km (16.9 miles)** with **32/36AH** which maximum speed upto **9.5 km/hr (5.6 mph).**

Substantial equivalence:

The **HOLI I scooter** is substantially equivalent to the **Be-Mobile 4-Wheeled Electric Scooter, DK S500 (K033239)** manufactured by **TUNG DENG ENTERPRISE CO., LTD.**.

Analysis of comparison of design, function and feature of **HOLI I scooter** to **TUNG DENG DK S500 (K033239)**, together with the results of compliance testing to existing ANSI/RESNA, ISO 7176 and IEC standards, demonstrate the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

While there are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do

they raise any new questions pertaining to safety or effectiveness. Therefore, **Smartech** believes that the **HOLI I** scooter is substantially equivalent to legally marketed devices currently in commercial distribution.

Non-Clinical testing

HOLI I scooter has been tested to wheelchair standards. They include:

(1). ANSI/RESNA WC/Vol.1 section 1-1998 / ISO7176-1-1999 Determination of static stability

(2). ANSI/RESNA WC/Vol.1 section 8-1998 / ISO7176-8-1998 Static, impact and fatigue strengths-Requirements and test methods

(3). ANSI/RESNA WC/Vol.2 section 21-1998 / ISO7176-21-2003 Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters

(4). CISPR 11-1990 Industrial, scientific and medical (ISM) Radio-Frequency equipment- electromagnetic disturbance characteristics – limits and methods of measurement

(5). IEC 61000-4-2-1995 EMC-Electrostatic discharge immunity test (ESD)

(6). IEC 61000-4-3-1995 EMC-Testing and measurement techniques-Radiated, RF, electromagnetic field immunity test

(7). California Bureau of Home Furnishings 116 Flammability Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chang Wan-Lan
Cycling and Health Tech. Industry R & D Center
Number 17, 37th Road
Taichung Industry Park
Taichung, China (Taiwan) 40768

Re: K050507
Trade/Device Name: HOLI I
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: June 9, 2005
Received: June 9, 2005

Dear Mr. Wan-Lan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **HOLI I**

Indications for Use:

The **HOLI I** scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use X Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K050507

(Posted November 13, 2003)